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McHugo

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(54) **CONTROLLED RELEASE AND RECAPTURE STENT-DEPLOYMENT DEVICE**

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(52) **U.S. Cl.**

CPC ***A61F 2/966*** (2013.01); *A61F 2002/9517* (2013.01); *A61F 2002/9528* (2013.01)

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See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

1,724,983	A	8/1929	Weiss
3,132,549	A	5/1964	Lee
3,888,258	A	6/1975	Akiyama
3,897,786	A	8/1975	Garnett et al.
4,559,041	A	12/1985	Razi
4,655,771	A	4/1987	Wallsten
4,921,484	A	5/1990	Hillstead
5,026,377	A	6/1991	Burton et al.
5,275,151	A	1/1994	Shockey et al.
5,372,600	A	12/1994	Beyar et al.

(Continued)

FOREIGN PATENT DOCUMENTS

CA	2739275	A1	4/2010
EP	566 807	A1	10/1993

(Continued)

OTHER PUBLICATIONS

Albee, F., "Bone Surgery with Machine Tools," Scientific American, Apr. 1936, pp. 178-181.

(Continued)

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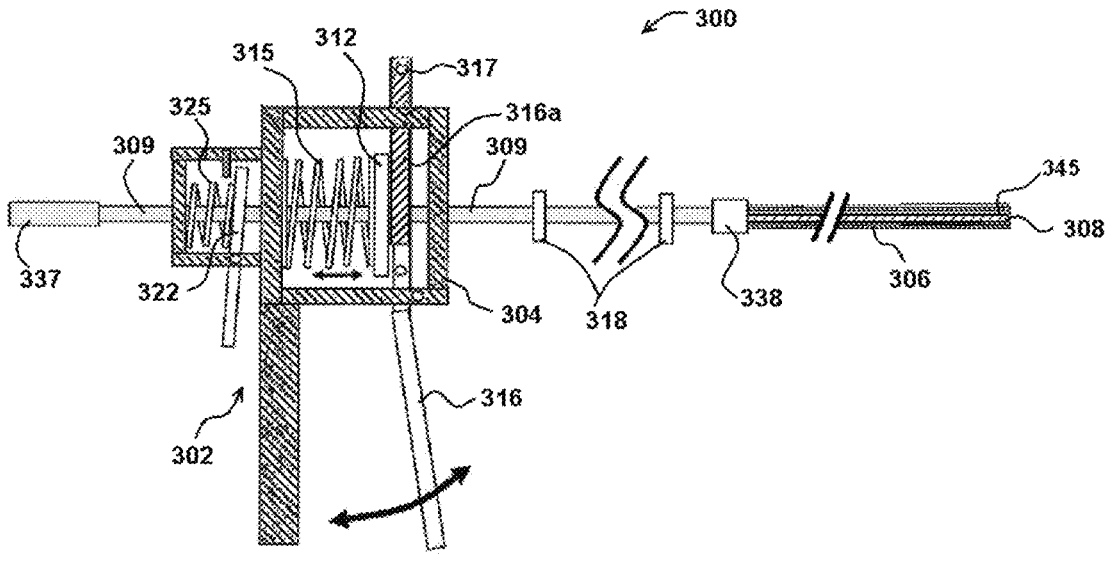
(57) **ABSTRACT**

A delivery device for deploying and resheathing an expandable prosthesis such as a stent. The delivery device includes a movable outer sheath and a fixed pusher/holder member that are configured for the sheath to retract in a proximal direction to release and/or to extend distally to resheath the stent. The device includes a spring-tensioned anti-backlash mechanism to accommodate any backlash elongation and/or compression of the pusher/holder member and sheath.

12 Claims, 3 Drawing Sheets



(56) **References Cited**

U.S. PATENT DOCUMENTS

5,415,664	A	5/1995	Pinchuk	
5,433,723	A	7/1995	Lindenberg et al.	
5,443,477	A	8/1995	Marin et al.	
5,458,615	A	10/1995	Klemm et al.	
5,554,894	A	9/1996	Sepielli	
5,681,323	A	10/1997	Arick	
5,683,451	A	11/1997	Lenker et al.	
5,690,644	A	11/1997	Yurek et al.	
5,700,269	A	12/1997	Pinchuk et al.	
5,702,418	A	12/1997	Ravenscroft	
5,707,376	A	1/1998	Kavteladze et al.	
5,709,703	A	1/1998	Lukic et al.	
5,733,325	A	3/1998	Robinson et al.	
5,759,186	A	6/1998	Bachmann et al.	
5,776,142	A	7/1998	Gunderson	
5,833,694	A	11/1998	Poncet	
5,906,619	A	5/1999	Olson et al.	
5,944,727	A	8/1999	Ahari et al.	
5,968,052	A	10/1999	Sullivan, III et al.	
5,993,460	A	11/1999	Beitelia et al.	
6,093,194	A	7/2000	Mikus et al.	
6,146,415	A	11/2000	Fitz	
6,162,231	A	12/2000	Mikus et al.	
6,168,610	B1	1/2001	Marin et al.	
6,238,402	B1	5/2001	Sullivan, III et al.	
6,254,628	B1	7/2001	Wallace et al.	
6,346,118	B1	2/2002	Baker et al.	
6,375,676	B1	4/2002	Cox	
6,383,211	B1	5/2002	Stachle	
6,391,050	B1	5/2002	Broome	
6,391,051	B2	5/2002	Sullivan, III et al.	
6,402,760	B1	6/2002	Fedida	
6,413,269	B1	7/2002	Bui et al.	
6,428,566	B1	8/2002	Holt	
6,514,261	B1	2/2003	Randall et al.	
6,520,983	B1	2/2003	Colgan et al.	
6,530,949	B2	3/2003	Konya et al.	
6,592,549	B2	7/2003	Gerdts et al.	
6,599,296	B1	7/2003	Gillick et al.	
6,629,981	B2	10/2003	Bui et al.	
6,669,719	B2	12/2003	Wallace et al.	
6,673,101	B1	1/2004	Fitzgerald et al.	
6,695,862	B2	2/2004	Cox et al.	
6,695,875	B2	2/2004	Stelter et al.	
6,749,627	B2	6/2004	Thompson et al.	
6,755,854	B2	6/2004	Gillick et al.	
6,755,855	B2	6/2004	Yurek et al.	
6,786,918	B1	9/2004	Krivoruchko et al.	
6,808,529	B2	10/2004	Fulkerson	
6,821,291	B2	11/2004	Bolea et al.	
6,860,898	B2	3/2005	Stack et al.	
6,866,669	B2	3/2005	Buzzard et al.	
6,890,317	B2	5/2005	Gerdts et al.	
6,893,458	B2	5/2005	Cox et al.	
6,911,039	B2	6/2005	Shiu et al.	
6,926,732	B2	8/2005	Derus et al.	
6,939,352	B2	9/2005	Buzzard et al.	
6,942,688	B2	9/2005	Bartholf et al.	
6,991,646	B2	1/2006	Clerc et al.	
7,052,511	B2	5/2006	Weldon et al.	
7,122,058	B2	10/2006	Levine et al.	
7,335,224	B2	2/2008	Øhlenschlæger	
8,932,342	B2 *	1/2015	McHugo et al.	623/1.11
2002/0007206	A1	1/2002	Bui et al.	
2002/0095203	A1	7/2002	Thompson et al.	
2002/0111666	A1	8/2002	Hart et al.	
2002/0183827	A1	12/2002	Derus et al.	
2003/0093084	A1	5/2003	Nissan et al.	
2003/0144671	A1	7/2003	Brooks et al.	
2003/0191516	A1	10/2003	Weldon et al.	
2003/0225445	A1	12/2003	Derus et al.	
2004/0006380	A1	1/2004	Buck et al.	
2004/0010265	A1	1/2004	Karpiel	
2004/0093057	A1	5/2004	Bolduc et al.	
2004/0181239	A1	9/2004	Dorn et al.	
2004/0186547	A1	9/2004	Dorn et al.	
2004/0193180	A1	9/2004	Buzzard et al.	
2004/0215229	A1	10/2004	Coyle	
2004/0220653	A1	11/2004	Borg et al.	
2004/0267282	A1	12/2004	Shkarubo et al.	
2005/0021123	A1	1/2005	Dorn et al.	
2005/0033402	A1	2/2005	Cully et al.	
2005/0033403	A1	2/2005	Ward et al.	
2005/0060016	A1	3/2005	Wu et al.	
2005/0060018	A1	3/2005	Dittman	
2005/0080476	A1	4/2005	Gunderson et al.	
2005/0085890	A1	4/2005	Rasmussen et al.	
2005/0090834	A1	4/2005	Chiang et al.	
2005/0090890	A1	4/2005	Wu et al.	
2005/0107862	A1	5/2005	Ohlenschlaeger	
2005/0113902	A1	5/2005	Geiser et al.	
2005/0131514	A1	6/2005	Hijlkema et al.	
2005/0149159	A1	7/2005	Andreas et al.	
2005/0177246	A1	8/2005	Datta et al.	
2005/0182475	A1	8/2005	Jen et al.	
2005/0209670	A1	9/2005	George et al.	
2005/0209685	A1	9/2005	Shifrin et al.	
2005/0240254	A1	10/2005	Austin	
2005/0256562	A1	11/2005	Clerc et al.	
2005/0273151	A1	12/2005	Fulkerson et al.	
2005/0288763	A1	12/2005	Andreas et al.	
2005/0288764	A1	12/2005	Snow et al.	
2005/0288766	A1	12/2005	Plain et al.	
2006/0004433	A1	1/2006	Greenberg et al.	
2006/0009858	A1	1/2006	Levine et al.	
2006/0184224	A1	8/2006	Angel	
2006/0184226	A1	8/2006	Austin	
2007/0060996	A1	3/2007	Goodin et al.	
2007/0060999	A1	3/2007	Randall et al.	
2007/0219614	A1	9/2007	Hartley	
2008/0300613	A1	12/2008	Shelton, IV et al.	
2009/0024133	A1	1/2009	Keady et al.	
2009/0030497	A1	1/2009	Metcalf et al.	
2009/0099640	A1	4/2009	Weng	
2010/0168834	A1	7/2010	Ryan et al.	
2010/0262157	A1	10/2010	Silver et al.	
2011/0190865	A1	8/2011	McHugo et al.	
2012/0172963	A1	7/2012	Ryan et al.	
2012/0221093	A1	8/2012	McHugo	

FOREIGN PATENT DOCUMENTS

EP	0747021	A2	12/1996
EP	1 525 859	A2	4/2005
JP	2005/532100	A	10/2005
JP	2007/508069	A	4/2007
WO	WO 98/53761	A1	12/1998
WO	WO 02/05885	A2	1/2002
WO	WO 2005/107644	A1	11/2005
WO	WO 2007/005799	A1	1/2007
WO	WO 2007/022395	A1	2/2007
WO	WO 2008/042266	A2	4/2008
WO	WO 2009/012061	A1	1/2009
WO	WO 2010/040009	A1	4/2010
WO	WO 2010/078352	A1	7/2010
WO	WO 2011/094527	A1	8/2011
WO	WO 2012/099731	A1	7/2012
WO	WO 2012/099732	A1	7/2012
WO	WO 2012/118638	A1	9/2012

OTHER PUBLICATIONS

International Search Report and the Written Opinion No. for Intl. No. PCT/US2012/020597, date of mailing May 21, 2012, 13 pgs.

International Search Report and Written Opinion of the International Searching Authority for International Application No. PCT/US2008/069019, dated Oct. 17, 2008, 9 pages.

International Search Report and Written Opinion of the International Searching Authority for International Application No. PCT/US2009/069721, dated Feb. 19, 2010, 9 pages.

(56) **References Cited**

OTHER PUBLICATIONS

International Search Report and Written Opinion of the International Searching Authority for International Application No. PCT/US2011/022903, dated Mar. 24, 2011, 9 pages.
International Search Report and Written Opinion of the International Searching Authority for International Application No. PCT/US2012/025895, dated Jun. 6, 2012, 12 pages.
International Search Report for International Application No. PCT/US2012/020598, dated May 10, 2012, 4 pages.
Office action from co-pending U.S. Appl. No. 12/649,046, dated Apr. 5, 2013, 11 pages.
Office action from Japanese Application No. 2011-544591, dated Oct. 29, 2013, 5 pages.

* cited by examiner

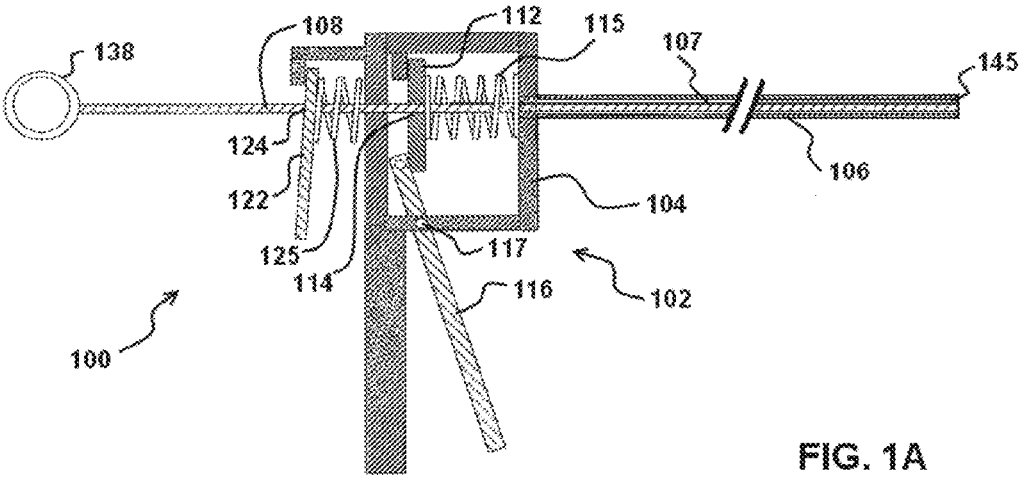


FIG. 1A

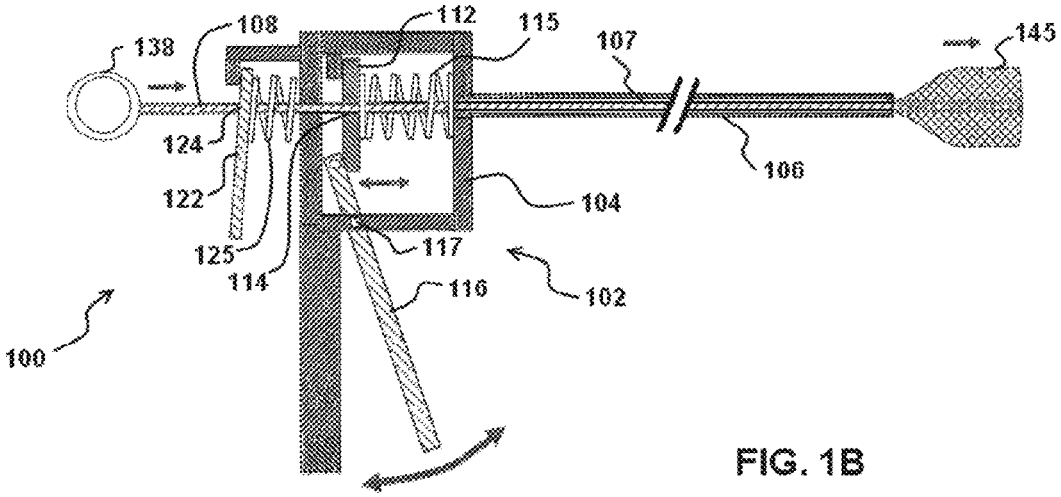


FIG. 1B

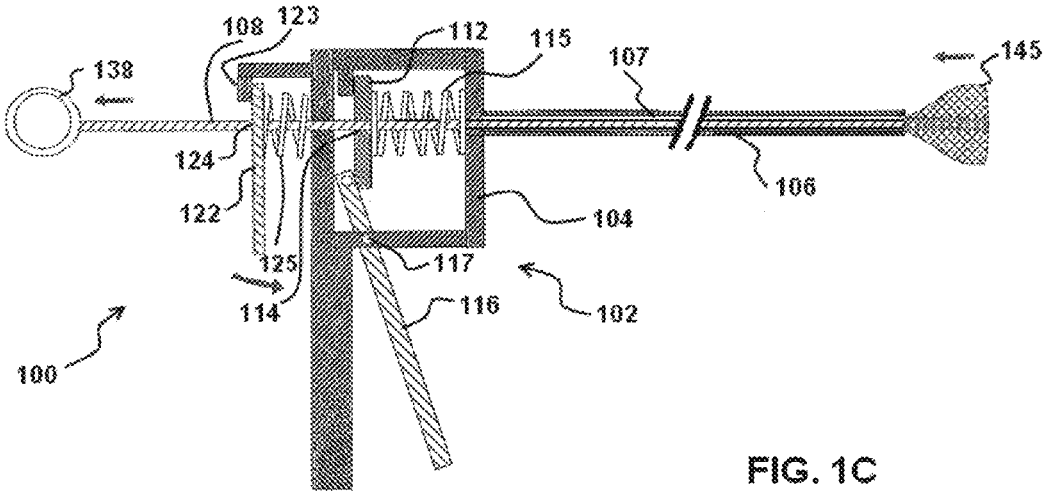


FIG. 1C

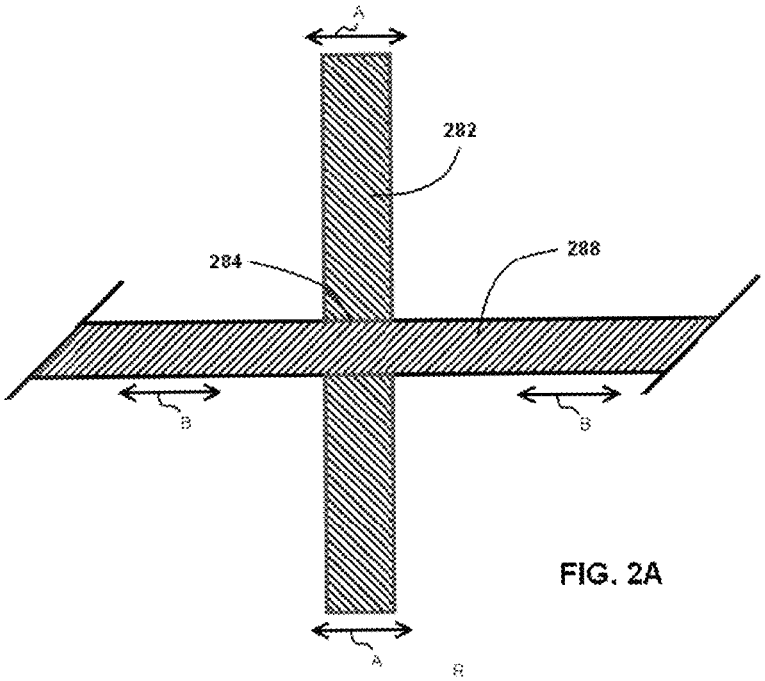


FIG. 2A

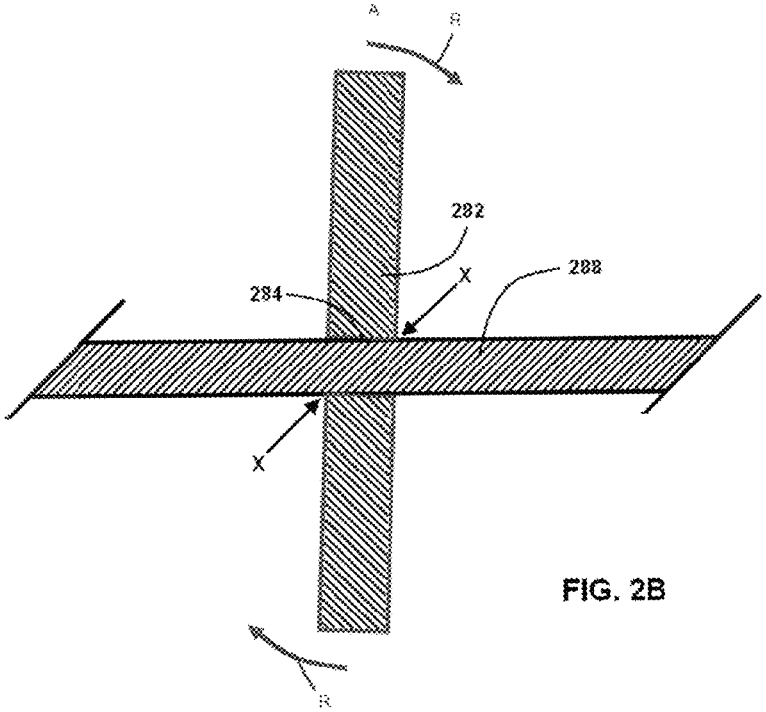


FIG. 2B

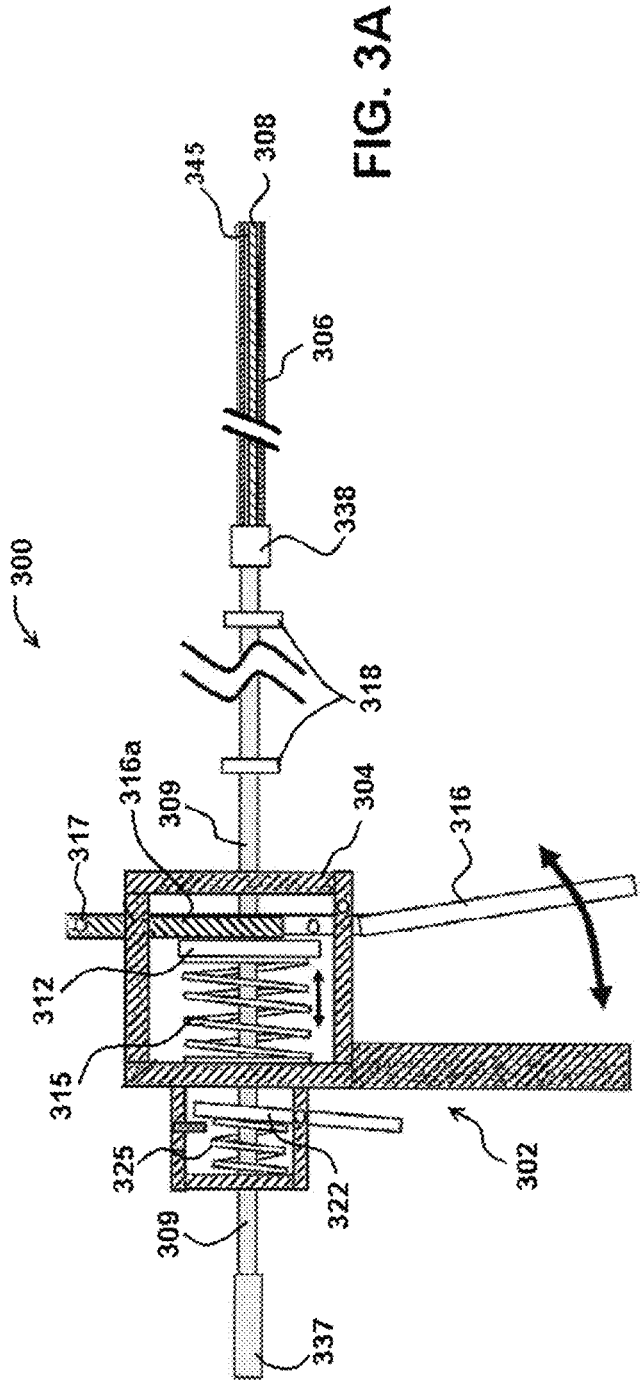

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FIG. 3A

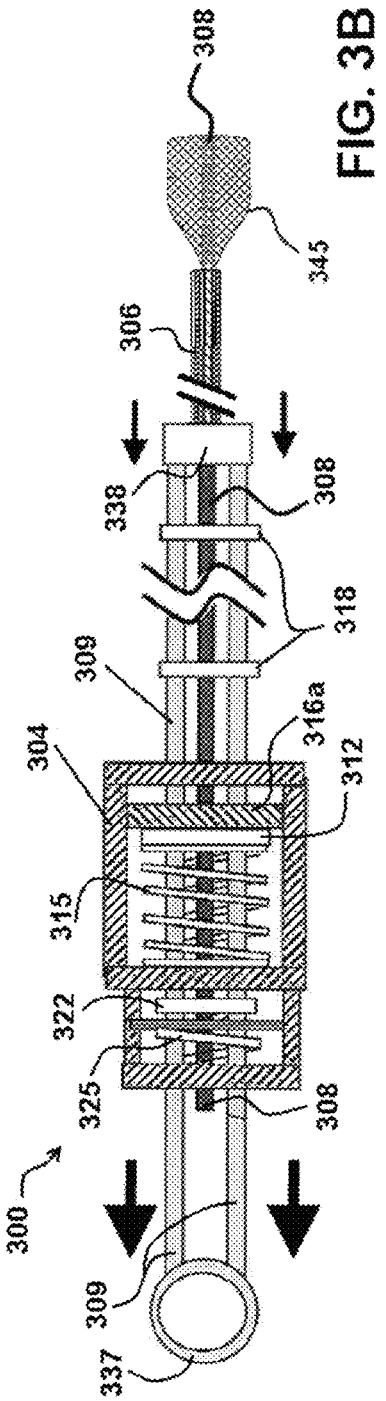
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FIG. 3B

CONTROLLED RELEASE AND RECAPTURE STENT-DEPLOYMENT DEVICE

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a non-provisional application which claims priority to U.S. provisional application Ser. No. 61/179,373, filed Mar. 13, 2013, which is incorporated by reference herein in its entirety.

TECHNICAL FIELD

This invention relates to a medical device and, in particular to a delivery device for a self-expanding prosthesis and a method of delivering and deploying the prosthesis into a body lumen.

BACKGROUND

A self-expanding prosthesis such as a stent may be introduced into a patient's body using a delivery device that includes a push-pull mechanism with an outer catheter coaxially slidably disposed over an inner catheter. The prosthesis is disposed in a circumferentially-restrained configuration at the distal end of the device between the inner catheter and the outer catheter. The prosthesis may be deployed by proximally pulling back the outer catheter relative to the inner catheter, exposing the prosthesis and allowing it to deploy/circumferentially expand.

The push-pull delivery device described above may have several shortcomings. For example, when using this conventional push-pull delivery device, a physician may inadvertently retract the outer catheter too far and prematurely deploy the prosthesis in an incorrect position within a body lumen. In that circumstance, repositioning the prosthesis may be difficult, if not impossible, because the prosthesis already will have radially self-expanded and engaged the body lumen.

Accordingly, there is a need for a delivery system that can increase the control, accuracy and ease of placement during deployment of a prosthesis. The embodiments described below may be useful for increasing the control, accuracy and ease of placement during deployment of the prosthesis and may also solve other problems.

SUMMARY

Accordingly, a delivery device is provided including a fixed pusher member and a longitudinally-movable outer catheter sheath that is configured to retract/advance in proximal/distal directions for deploying and recapturing/resheathing an intraluminal prosthesis.

BRIEF DESCRIPTION OF THE DRAWINGS

Embodiments are described by way of example with reference to the accompanying drawings, in which:

FIGS. **1**A-**1**C show a partial section view of a delivery device embodiment and method of use;

FIGS. **2**A-**2**B show a diagrammatic section view of plate/pusher member interaction; and

FIGS. **3**A-**3**B show a partial section view of another delivery device embodiment and method of use.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The embodiments are described with reference to the drawings in which like elements are generally referred to by like numerals. The relationship and functioning of the various elements of the embodiments may be understood by reference to the drawings and the following detailed description. However, the embodiments described below are provided by way of example only, and the invention is not limited to the embodiments illustrated in the drawings. It should also be understood that the drawings are not to scale, and—in certain instances—details have been omitted that are not necessary for an understanding of the embodiments such as conventional details of fabrication and assembly.

Throughout the specification, the terms "distal" and "distally" shall denote a position, direction, or orientation that is generally away from the physician (including any other person holding/operating a device) and/or toward a treatment zone/patient. Accordingly, the terms "proximal" and "proximally" shall denote a position, direction, or orientation that is generally towards the physician. In FIGS. **1**A-**1**C and **3**A-**3**C, "distal" is generally to the right, and "proximal" is generally to the left. Various other constructions of deployment devices and methods may be understood with reference to U.S. Pat. App. Pub. Nos. 2012/0029607 and 2010/0168834, each of which is incorporated by reference herein in its entirety. Those of skill in the art will appreciate, with reference to the present disclosure, the novel ways in which the presently described structures may be used with the stent deployment devices and methods disclosed therein.

Referring now to the drawings in FIGS. **1**A-**3**B, embodiments of a delivery device for deploying a self-expanding prosthesis are shown. As will be discussed, the delivery device is configured with the ability to resheath and reposition the prosthesis, thereby substantially increasing the control and accuracy of a deployment process as compared with conventional delivery devices.

FIGS. **1**A-**1**C show one embodiment of a delivery device **100**, with reference to a method of use. The delivery device **100** includes a handle **102** with a handle body **104** and an elongate tubular sheath **106** fixedly attached to and extending distally from the handle body **104**. An elongate pusher member **108** extends slidably through a longitudinal lumen **107** of the sheath **106**. The handle body **104** is shown in a longitudinal cutaway view revealing the internal components of the handle **102**.

The interior of the handle **102** includes an advancement plate member **112** that is biased toward the proximal end of the pusher member **108**. In this embodiment, the advancement member **112** is shown as being biased by a coil spring **115**, but other biasing means known in the art may be used. The advancement member **112** includes an advancement member aperture **114** through its thickness, through which the pusher member **108** extends. A trigger member **116** is pivotably mounted to the handle body **104** and is connected to or otherwise disposed in operative contact with the advancement member **112**. When the pivot axis **117** is configured as shown, pivoting the lower portion of the trigger member **116** proximally toward the handle body **104** will pivot the upper portion of the trigger member **116** distally, pushing the advancement member **112** distally. When advanced distally by motivation from the trigger member **116**, the advancement member **112** engages (in the manner described below with reference to FIGS. **2**A-**2**B) and pushes distally the pusher member **108**.

A keeper plate member **122** is also mounted to the handle body **104** and biased toward its proximal end against a keeper stop **123**. In this embodiment, the keeper member **122** is shown as being biased by a coil spring **125**, but other biasing means known in the art may be used. The keeper member **122** includes a keeper member aperture **124** through its thickness,

through which the pusher member **108** extends. The keeper member functions as a "parking brake" or retaining means that will prevent proximal movement of the pusher member **108** when engaged thereto. This may be needed because, as a stent is deployed distally, the sheath **106** may stretch distally and then—when attempting to relax and return to its original length—it may introduce backlash that would drive the pusher **108** proximally if it weren't held in place.

The proximal end of the pusher member **108** may include a handle or other grasping portion such as a ring **138** that will facilitate a user grasping the pusher member **108** and moving it proximally and/or distally (albeit in a generally less controlled fashion than by employing the advancement and keeper/retractor members **112**, **122**). A distal portion of the pusher member **108** is attached to an expandable prosthesis such as, for example, an intraluminal device embodied as a self-expanding stent **145** (which, because it is sheathed in lumen **107** is not clearly visible in FIG. **1**A). The stent **145** may be constrained by this attachment and/or by the sheath **106**. In certain embodiments, the sheath and pusher member will be sufficiently flexible and elongate to introduce a prosthetic device into a patient's alimentary canal. For example, the device **100** may be used to introduce a stent into a patient's esophagus (e.g., via the patient's mouth) or along an intestinal lumen. Device embodiments may be used through natural and/or surgically-created orifices, and may be practiced on a scale suitable for vascular stenting. It should be appreciated that the self-expanding prosthesis may include one or more stents such as, for example, in a stent-graft structure that includes one or more stents supporting graft material.

FIGS. **2**A-**2**B illustrate the principle of operation of the attachment member **112** and the keeper member **122** with pusher member **108** (as well as analogous components of the other embodiments herein). The operation is described with reference to an apertured locking/gripping plate **282** (analogous to those members **112**, **122**, which function in the same manner) and a through-rod **288** (analogous to the pusher member **108**, which functions in the same manner). The locking plate **282** includes an aperture **284** through its thickness. The inner diameter of the aperture **284** is preferably about the same or somewhat greater than an outer diameter of the through-rod **288**.

As shown in FIG. **2**A, when the long axis of the through-rod **288** is fully or nearly parallel or coaxial with the long axis of the aperture **284**, the through-rod **288** can pass freely along its longitudinal axis through the aperture **284** (as indicated by linear motion arrows B), and/or the plate **282** may move freely along a length of the rod **288** (as indicated by linear motion arrows A). However, as shown in FIG. **2**B, when the long axis of the aperture **284** is inclined at a sufficient angle relative to the long axis of the through-rod **288** (indicated by rotary motion arrows R), the border of the aperture grips, captures, binds, and/or otherwise engages an exterior surface of the through-rod **288** (e.g., in the regions indicated by designator arrows X), preferably with sufficient force to substantially or completely prevent the through-rod **288** from moving longitudinally relative to the locking plate **282**.

In other words, when the aperture **284** is perpendicular to the long axis of the locking plate **282**, the through-rod **288** can move freely therethrough when it is perpendicular to the locking plate **282**, but will be engaged by the aperture when it is at a non-perpendicular angle relative to the locking plate. In the embodiments described here, the relative angle of a locking plate/keeper member to a through-rod/pusher member is also controlled by a spring-biased angle of the locking plate/keeper member. Those of skill in the art will appreciate from the figures that such an arrangement will allow free movement in one direction as contact/friction between the through-rod/pusher member and aperture of the locking plate/keeper member in one direction will move them generally perpendicular relative to each other, while movement in the opposite direction will angle them non-perpendicularly and thereby lock them together. Similarly, when the locking plate **282** is functioning as an advancement member (e.g., advancement member **112**), the plate **282** may be angled to engage the rod **288** and then pushed in a direction coaxial with the rod's long axis such that the plate **282** will move the rod in the direction the plate is moved.

The external geometry of the through-rod **288** and the aperture **284** do not need to be the same (e.g., the aperture may be—for example—hexagonal, square, or circular, while the cross-sectional geometry of the through-rod may be—for example—elliptical, triangular, or pentagonal). This type of securement is well-known in the art and those of skill in the art will appreciate that various shapes of apertures and/or through-rods may be used within the scope of the present invention, including that the through-rod may be notched or otherwise frictionally-enhanced.

FIG. **1**A shows the device **100** in an unactuated state, with the stent **145** being sheathed. Actuation of the device **100** with stent deployment is described with reference to FIG. **1**B. To actuate the device **100** and advance the pusher member **108** distally, a user will pivot the lower portion of the trigger **116** toward the handle body **104**. This action inclines the advancement member **112** to a first angle where its aperture captures/engages the pusher member **108** and pushes it forward/distally. During this action, the keeper member **122** is disposed at an angle wherein its aperture **124** allows freely sliding distal-ward passage of the pusher member **108** therethrough. When the trigger **116** is released, the proximal bias of the advancement member **112** moves it back to the default position shown in FIG. **1**A. At the same time, the proximal bias of the keeper member **122** generally retains it in the default position shown in FIG. **1**A. Serial actuation of the trigger **116** will advance the pusher member **108** and overlying stent **145** distally out of the distal end of the sheath **106** as shown in FIG. **1**B.

During deployment of a stent **145** (e.g., into a patient's esophagus), it may be desirable or even needful to reposition the stent longitudinally or otherwise. When the stent **145** has been partially deployed such that it has expanded sufficiently to engage patient tissue, it may be difficult or impossible to move the stent longitudinally and/or rotationally without injuring the patient and/or damaging the stent if it remains expanded. The present device **100** provides for a resheathing function, described with reference to FIG. **1**C. As is known in the art, the stent **145** and deployment device **100** may be visualized during a stent-placement procedure by ultrasound and/or fluoroscopy (e.g., based upon the construction of the stent and/or inclusion of specific markers such as echogenic and/or radio-opaque markers included in/on the stent, the device, or any combination thereof). Such visualization, which may also be done using a camera-type device (e.g., optical or electronic endoscope), will enable a physician to monitor and carefully control deployment and—if needed—resheathing/recapture of an expandable prosthesis such as a stent, stent-graft, or other prosthetic device.

If, during deployment, it becomes desirable to partially or completely resheath the stent **145**, thereby reducing its outer diameter sufficiently to allow it to be repositioned without damaging the stent or surrounding tissue, a user may actuate (i.e., disengage the brake function of) the keeper member **122** by moving it to an angle generally perpendicular to the pusher

member **108**, which will release the pusher **108** and allow it to be moved proximally by the user pulling proximally on the loop **138**.

In another aspect, the keeper **122** may function as a resheathing trigger. To actuate the keeper **122** in its function as a resheathing trigger and thereby retract the pusher member **108** proximally, a user will pivot the lower portion of the keeper **122** toward the handle body **104** sufficiently to release its engagement with the pusher **108** and then slide the keeper member **122** distally along the pusher **108**. When it contacts the handle body **104**, the user may then allow the keeper **122** to incline back to a first angle where its aperture captures/engages the pusher member **108** and pulls it (pusher **108**) back/proximally (or, more accurately, is pushed back proximally by the bias of the spring **125**). Specifically, when the keeper **122** is released, its proximal bias moves it back to the default position shown in FIG. **1**A.

The proximal bias of the advancement member **112** by spring **115** generally retains it in the default position shown in FIG. **1**A, disposed at an angle wherein its aperture **114** allows freely sliding distal-ward passage of the pusher member **108** therethrough. The device may be constructed such that serial actuation of the keeper **122** will retract the pusher member **108** and overlying stent **145** proximally back into the distal end of the sheath **106** as shown in FIG. **1**C, which shows the stent **145** having been partially resheathed. Thereafter, the longitudinal position of the device **100** (with the sheathed stent **145**) may be adjusted as desired, and the stent deployed as desired, in the manner described above with reference to FIGS. **1**A-**1**B.

FIGS. **3**A-**3**B show another embodiment of a delivery device **300**, with reference to a method of use. The delivery device **300** includes a handle **302** with a handle body **304** and an elongate tubular sheath **306** fixedly attached to and extending distally from a sheath-attached puller **338** that extends slidably through the handle body **304**. An elongate pusher/holder member **308** extends slidably through a longitudinal lumen **307** of the sheath **306**, but is fixed relative to the handle body **304**. The handle body **304** is shown in FIG. **3**A in a side view revealing internal components of the handle **302**. FIG. **3**B shows a top view of the device **300** of FIG. **3**A, with the sheath-attached puller **338** having been retracted proximally to actuate the device and release a distal portion of the stent **345**.

The interior of the handle **302** includes an advancement plate member (also functioning as a retaining member) **312** that is biased toward the distal end of the stent-holder member **308**. In this embodiment, the retaining member **312** is shown as being biased distally by a coil spring **315**, but other biasing means known in the art may be used. The retaining member **312** is longitudinally freely movable along/relative to the holder member **308** and to the sheath-attached puller **309**. A deployment/advancement trigger member **316** is pivotably mounted to the handle body **304** and the portion **316***a* of it inside the handle body **304** is contacted by the retaining member **312**. That body-internal trigger portion **316***a* moves freely relative to the inner holder member **308** and is configured to engage the sheath-attached puller **309** only during a proximal stroke, but to reciprocate freely back to the more distal position shown in FIG. **3**A when released and moved back to that position by the bias of the spring **315**. Alternatively, or in addition, the retaining member **312** may engage the sheath-attached pulling member only when being moved proximally to pull it back upon actuation of the trigger **316**, then freely reciprocate distally back along it to the position shown in FIG. **3**A. When the pivot axis **317** is configured as shown, a user pivoting the lower portion of the trigger member **316** proximally will pull the retaining member **312** and the sheath-attached puller **309** both proximally. The advancement/retainer member **312** includes two apertures (not shown) through which the puller **309** passes.

A keeper member **322** (which serves also to accommodate and prevent any backlash introduced by stretching and/or compression of the holder member **308**) is mounted within an upper portion of the handle body **304** and biased toward its distal end. In this embodiment, the keeper member **322** is shown as being biased by a distally/pushing-tensioned coil spring **325**, but other biasing means known in the art may be used. The pusher member **308** extends through the keeper member **322** without being bound thereto. The keeper member **322** is also in mechanical communication with the sheath-attached puller **309**, and—unless the keeper member **322** is rotated against its spring-bias—it contacts the sheath-attached puller **309** in a manner that prevents distal motion of the sheath-attached puller **309**.

A distal portion of the pusher/holder member **308** is attached to or otherwise in releasable contact with an expandable prosthesis such as, for example, a self-expanding stent **345**. The attachment may include one or more an abutment, attachment with wire(s) or the like, the stent being concentrically constricted around the member **308**, or any other means. The stent **345** may be constrained by this attachment and/or by the sheath **306**. A variety of methods and constructions are known and are being developed in the art for providing stent attachment and deployment from a central pusher member whether or not it is accompanied by an outer sheath. Many of these constructions and methods may be practiced in a useful manner within the scope of the present invention, one advantage of which is generally a more compact construction than other devices configured to perform the same or similar functions. One or more stabilizer elements **318** may be provided, attaching the sheath-attached puller member **309** slidably to the holder member **308**. Although the stent-holder member **308** is longitudinally fixed relative to the handle body **304**, the sheath **306** (which coaxially surrounds a distal length of the holder **308**) is longitudinally slidable relative to the holder **308**.

FIG. **3**A shows the device **300** in an unactuated state, with the stent **345** being sheathed (and therefore not clearly visible in FIG. **3**A). Actuation is described with reference to the top view of FIG. **3**B. To actuate the device **300** and retract the sheath **306** proximally, a user will pivot the lower portion of the deployment trigger **316** toward the downward extending portion of the handle body **304**. This action captures/engages the sheath-attached puller member **309** and pulls it proximally. One advantage of this embodiment is that such actuation can be completed with only one hand, which will provide clear advantages to treatment personnel using the device. Another advantage of this embodiment is that the handle remains in a fixed position relative to the expandable member **345** and relative to the patient's body (i.e., only the sheath moves longitudinally during actuation). During this action, the keeper member **322** is disposed at an angle wherein it allows freely sliding distal-ward passage of the sheath-attached puller member **309** therethrough. When the deployment trigger **316** is released, the distal bias of the retaining member **312** against the in-handle portion **316***a* of the trigger **316** moves it back to the default position shown in FIG. **3**A. At the same time, the distal bias of the keeper member **322** generally retains it in the default position shown in FIG. **3**A without retracting the pusher member **308**. In this manner, it functions as a "parking brake" preventing undesired motion due to backlash in system components. Serial actuation of the deployment trigger **316** will retract the sheath-attached puller

member **309** and release the stent **345** distally out of the distal end of the sheath **306** as shown in FIG. **3**B.

Those of skill in the art will appreciate, with reference to the present disclosure, that the embodiment of FIGS. **3**A-**3**B may be manually/directly actuated by depressing both the trigger **316** and the keeper member **322**. (However, neither element may need to be actuated in practice to effect deployment.) Then, the proximal-end ring **337** of the sheath-attached puller member **309** can be pulled to retract the sheath and deploy the stent **345**. The central pusher/holder member **308** may be constructed as a catheter including one or more lumens configured to allow passage of, for example, a wire guide, contrast fluid, or other useful tools or materials. The sheath **306** and pusher/holder member **308** are dimensioned and are sufficiently flexible and elongate to introduce a prosthetic device such as a stent into a patient's alimentary canal. The trigger **316** and keeper **322** can also be actuated in a manner allowing the sheath-attached puller member **309** to be advanced distally to re-sheath a partially-unsheathed stent **345** to allow for repositioning, if needed. Those of skill in the art will also appreciate that the present configuration for use with a "pistol grip"/"power grip" may readily be modified within the scope of the present disclosure to implement with use of an "internal precision grip."

The above figures and disclosure are intended to be illustrative and not exhaustive. This description will suggest to one of ordinary skill in the art many variations and alternatives that may be practiced within the scope of the present invention, including that many features described herein may be used in other embodiments described. Those familiar with the art may recognize other equivalents to the specific embodiments described herein which equivalents are also intended to be encompassed by the attached claims. Furthermore, the advantages described above are not necessarily the only advantages of the invention, and it is not necessarily expected that all of the described advantages will be achieved with every embodiment of the invention. The scope of the present invention is defined by the claims directed thereto.

I claim:

1. A controlled release and recapture prosthetic deployment device comprising:

a handle including a handle body;

a tubular sheath;

a sheath-attached puller extending slidably through the handle body and fixedly attached to the sheath; and

an elongate stent-holder member fixedly extending through and distally out from the handle body, and further extending through a longitudinal lumen of the sheath, which sheath is slidable relative to the stent-holder member;

wherein the handle comprises:

a retaining member in the handle body, where the retaining member is biased toward a distal end of the device;

a keeper member in the handle body, where the keeper body releasably engages the sheath-attached puller and is also biased toward the distal end of the device; and

a first trigger member,

pivotable relative to the handle body,

disposed in mechanical communication with the retaining member, and

configured to move the retaining member and the sheath-attached puller proximally when the trigger member is pivoted in a first direction.

2. The device of claim **1**, further comprising a self-expanding prosthesis removably disposed within a distal portion of the sheath and attached to the holder member.

3. The device of claim **2**, where the self-expanding prosthesis comprises a stent.

4. The device of claim **2**, where the self-expanding prosthesis comprises a stent graft.

5. The device of claim **1**, wherein the sheath-attached puller includes a proximal graspable structure configured for manual direct proximal retraction of the puller.

6. The device of claim **1**, further comprising at least one stabilizer element connected to the sheath-attached puller and the holder member.

7. The device of claim **1**, further comprising a self-expanding prosthesis removably disposed within a distal portion of the sheath, and configured wherein actuation of the trigger member moves the sheath proximally relative to the prosthesis, releasing the prosthesis from constraint by the sheath.

8. The device of claim **1**, wherein the sheath and holder member are sufficiently flexible and elongate to introduce a prosthetic device into a patient's alimentary canal.

9. The device of claim **8**, wherein the sheath and holder member are sufficiently flexible and elongate to introduce a prosthetic device into a patient's esophagus via the patient's mouth.

10. The device of claim **1**, where the keeper body is also biased toward the distal device end by a spring.

11. The device of claim **1**, where the keeper member includes a second trigger portion attached pivotably to the handle body.

12. The device of claim **1**, where the handle body is configured for use with a power grip.

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